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| 10/585,329 | 07/06/2006 | Karine Caumont-Bertrand | BJS-3665-186 | 2862 |
| 23117 7590 09/18/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | | |
| EXAMINER SHIAO, REI TSANG | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/585,329

Applicant(s)

CAUMONT-BERTRAND ET AL.

Examiner

REI-TSANG SHIAO

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-32 and 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
- Paper No(s)/Mail Date 7/6/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

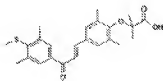
1. This application claims benefit of the foreign applications:
France 0400123 with a filing date 01/08/2004; and France 0409257 with a filing date 09/01/2004. However, English-translated versions of the certified foreign priority documents have not been filed to the Office, the instant foreign priority has not been granted.
2. Claims 19-36 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement filed on July 06, 2006 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of election of Group II claims 19-32 and 34-36, in part, in the reply filed on July 10, 2008 is acknowledged. Election of a compound,



i.e., _____, as the single species is also acknowledged. The traversal is on the grounds that The cited Wang et al. (i.e., CAS: 148:379286) is not prior art to the presently claimed invention and can not be the basis for establishing that the presently claimed invention allegedly fails to define a contribution over the art.

This is found not persuasive, and the reasons are given *infra*.

Claims 19-36 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 19-32 and 34-36, in part, drawn to compounds of formula (I), wherein the variable R_i or R'_i does not represent heterocycle group thereof.

The claims 19-36 herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, see Najib et al. CAS: 2004-180204. Shibata et al. disclose similar diphenyl compounds as the instant compounds of formula (I). Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Furthermore, even if unity of invention under 37 CFR 1.475(a) is not lacking, which it is lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product', or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

However, it is noted that unity of invention is considered lacking under 37 CFR 1.475(a) and (b). Therefore, since the claims are drawn to more than a product, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims lack unity of invention and should be limited to only a product, or a process for the preparation, or a use of the said product. In the instant case, Groups I-III are drawn to various products, processes of making, and the final products do not contain a common technical feature or structure, and do not define a contribution over the prior art, i.e., similar compounds having aryl moiety. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 19-32 and 34-36, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 19-32 and 34-36, in part, not embraced in above elected subject matter, and claim 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising compounds of formula (I), does not reasonably provide enablement for the instant methods of use for the instant compositions for treating cardiovascular diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention of claim 36 is drawn compositions comprising compounds of formula (I) with intent methods of use for treating diseases.

The state of the prior art and the predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the chemical art is unpredictable, requiring each embodiment to be individually assessed for chemical activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming compounds of the formula of claim 36 with intent methods of use for treating diseases (i.e., cardiovascular diseases). As such, the specification fails to enable the skilled artisan to use the all compounds of claim 36 effective to "treating diseases (i.e., cardiovascular diseases)".

Hence, one of skill in the art is unable to fully predict possible results from the administration of the compositions comprising compounds of formula (I) due to the unpredictability of the "treating diseases (i.e., cardiovascular diseases)". The "treating diseases (i.e., cardiovascular diseases)" is known to have many obstacles that would prevent one of ordinary skill in the art from accepting reaction regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of exemplary tests of anti-oxidation, PPAR activation and lipid metabolism, see Examples of pages 88-102 of the specification. There are no working examples present for "treating diseases (i.e., cardiovascular diseases)" by the all compounds of claim 36 of the instant invention.

The breadth of the claims

The breadth of the claims is the instant compounds with intent methods of use effective to "treating diseases (i.e., cardiovascular diseases)". Moreover, there is no reasonable basis for assuming the instant compounds of formula (I) embraced by the claims will share the same chemical properties.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what "treating diseases (i.e., cardiovascular diseases)" would be benefited by the instant compounds of formula (I) of the instant invention and would furthermore then have to determine which of the claimed methods of use would provide "treating diseases (i.e., cardiovascular diseases)", if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be

individually assessed for physiological activity screening to determine which methods of use exhibit the desired chemical activity and which "treating diseases (i.e., cardiovascular diseases)", would benefit from this activity. Thus, the specification fails to provide sufficient support of the broad use of the compounds of the instant claims for the "treating diseases (i.e., cardiovascular diseases)".

As a result necessitating one of skill to perform an exhaustive search for which "treating diseases (i.e., cardiovascular diseases)", can be used by what compounds of the instant claims in order to practice the claimed invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds in regards to the "treating diseases (i.e., cardiovascular diseases)", one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to

engage in undue experimentation, with no assurance of success. This rejection can be overcome by deleting the preamble "for the treatment of cardiovascular diseases,skin ageing" from claim 36, would obviate the rejection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 32 and 35, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Deletion of the limitation "such as" would obviate the rejection.

Claim Rejections - 35 USC § 102

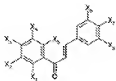
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 19-32 and 34-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Najib et al. CAS:2004-180204.

Applicants claim compounds/composition of formula (I), i.e.,



, see claim 19.

Najib et al. disclose a number of compounds, see DCR-854883, DCR-854884, DCR-854889, DCR-854905, DCR-854906, DCR-854908, DCR-854911, DCR-854912, DCR-854919, DCR-854920, DCR-854921, or DCR-854922. They clearly anticipate the instant compounds of formula (I), wherein the variable X7 represents G7-R7, and G7 is oxygen, and R7 represents substituted alkyl. Dependent claims 20-32 and 34-36 are also rejected along with claim 19 under 35 U.S.C. 102(a).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

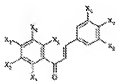
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Najib et al. CAS:2004-180204.

Applicants claim compounds/composition of formula (I), i.e.,



, see claim 19.

Determination of the scope and content of the prior art (MPEP §2141.01)

Najib et al. disclose a number of compounds, see DCR-854883, DCR-854884, DCR-854889, DCR-854905, DCR-854906, DCR-854908, DCR-854911, DCR-854912, DCR-854919, DCR-854920, DCR-854921, or DCR-854922.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between instant claims and Najib et al. is that the instant variable X5 represents halogen or alkoxy, while Najib et al. represents alkoxy at the same position. The compounds of Najib et al. overlap with the instant invention.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 19-32 and 34-36 prima facie obvious because one would be motivated to employ the processes of Najib et al. to obtain instant compounds of formula (I). Dependent claims 20-32 and 34-36 are also rejected along with claim 19 under 35 U.S.C. 103(a).

The motivation to make the claimed processes derived from the known processes of Najib et al. would possess similar activity (I.e., compositions) to that which is claimed in the reference.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

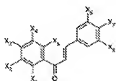
1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-32 and 34-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 38 of Najib et al. co-pending application No. 10/520,078, or claim 69 of co-pending application No. 10/520,078. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compounds/composition of formula (I), i.e.,



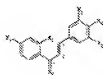
, see claim 19.

Najib et al. '078 or '079 independently claim compounds/compositions of formula



(I), i.e.,

or



(II)

The difference between instant claims and Najib et al. '078 or '079 is that the instant variable X5 represents halogen or alkoxy, while Najib et al. represents alkoxy at the same position. The compounds of Najib et al. overlap with the instant invention.

One having ordinary skill in the art would find the claims 19-32 and 34-36 *prima facie* obvious because one would be motivated to employ the processes of Najib et al. to obtain instant compounds of formula (I). Dependent claims 20-32 and 34-36 are also rejected along with claim 19 under 35 U.S.C. 103(a).

The motivation to make the claimed processes derived from the known processes of Najib et al. would possess similar activity (i.e., compositions) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims Objection

10. Claims 19-32 and 34-36 are objected to as containing non-elected subject matter, i.e., heterocycle, tetrazole, [1,2]dithiolane, morpholine, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Rei-tsang Shiao, Ph.D.
Primary Patent Examiner
Art Unit 1626

September 15, 2008